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Voluntary    Public

**Date:** 3/3/2017

**GAIN Report Number:** IN7036

## India

**Post:** New Delhi

### **GOI Notifies Microbiological Standards for Fish and Fishery Products**

**Report Categories:**

Fishery Products

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

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**Report Highlights:**

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published official gazette notification for Food Safety and Standards (Food Products Standards and Food Additives) Third Amendment Regulations, 2017, which defines the microbiological standards for fish and fish products. The regulation has not been notified to the World Trade Organization (WTO) to date.

## **General Information:**

**Disclaimer:** The information contained in this report was retrieved from the GOI website: <http://www.fssai.gov.in/>. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity. The summary below is based on a  *cursory* review of the subject announcement and, therefore, should not under any circumstances be viewed as a definitive interpretation of the regulation in question, or of its implications for U.S. agricultural trade interests.

On February 14, 2017, the Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) notified Food Safety and Standards (Food Products Standards and Food Additives) Third Amendment Regulations, 2017 to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. The new regulation defines the microbiological standards for fish and fish products. The draft microbiological standards for the same were earlier notified to the WTO on January 4, 2016 for comments (please see [IN6012](#)).

The full text of the regulation is pasted below or can be accessed at [Final Gazette Notification of Food Safety and Standards \(Food Product Standards and Food Additives\) Third Amendment Regulation, 2017 related to microbiological standards for fish and fish products](#) on the FSSAI website. The regulation has not been notified to the World Trade Organization (WTO) to date.

## **Final details on the regulation:**

Type of Regulation: Final

GOI Publication Date: February 14, 2017 (Date of Publication in Official Gazette)

WTO Notification Date: Not notified (as of February 3, 2017)

Date of Implementation: January 1, 2018

Products Affected: Fish and Fishery Products

Agency in Charge: Food Safety and Standards Authority of India, GOI



# भारत का राजपत्र The Gazette of India

असाधारण  
EXTRAORDINARY  
भाग III—खण्ड 4  
PART III—Section 4  
प्रधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 47]  
No. 47]

नई दिल्ली, मंगलवार, फरवरी 14, 2017/माघ 25, 1938  
NEW DELHI, TUESDAY, FEBRUARY 14, 2017/MAGHA 25, 1938

स्वास्थ्य और परिवार कल्याण मंत्रालय  
(भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)  
अधिसूचना  
नई दिल्ली, 13 फरवरी, 2017

फा. सं. 1-10(7)/स्टैंडर्ड्स/एसपी(मत्स्य और मत्स्य उत्पाद) एफएसएसआई- 2013.— जबकि खाद्य सुरक्षा और मानक (खाद्य उत्पाद मानक और खाद्य सहयोग्य) संशोधन विनियम, 2015 का प्रारूप खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 की उपधारा (1) के अधिनियम द्वारा भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की

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## MINISTRY OF HEALTH AND FAMILY WELFARE (Food Safety and Standards Authority of India)

### NOTIFICATION

New Delhi, the 13<sup>th</sup> February, 2017.

**F.No.1-10(7)/Standards/SP (Fish & Fisheries Products)/FSSAI-2013.**— Whereas the draft of the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016, were published as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F.No.1-10(7)/Standards/SP (Fish & Fisheries Products)/FSSAI-2013, dated the 12<sup>th</sup> January, 2016 in the Gazette of India, Extraordinary, Part III, section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 28<sup>th</sup> January, 2016;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with sub-section (2) of section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

### REGULATIONS

1. **Short title and commencement.**— (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Third Amendment Regulations, 2017.

(2) These regulations shall come into force on 1<sup>st</sup> January, 2018.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in APPENDIX B, relating to "Microbiological Requirements", for the TABLE 1 and the entries relating thereto, the following Tables and the entries shall respectively be substituted, namely:-

**"Table 1A**  
**Microbiological Requirements for Fish and Fishery products -Hygiene Indicator Organisms**

Sl. No.	Product Category*	Aerobic Plate Count				Coagulase positive Staphylococci				Yeast &mold count				Stage where criterion applies	Action in case of unsatisfactory results
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)			
		n	c	m	M	n	c	m	M	n	c	m	M		
1.	Chilled/Frozen Finfish	5	3	5x10 <sup>5</sup>	1x10 <sup>7</sup>	-	-	-	-	-	-	-	-	After Chilling/Freezing.	Improvement in hygiene; Time-Temperature Control along value chain
2.	Chilled/Frozen Crustaceans	5	3	1x10 <sup>6</sup>	1x10 <sup>7</sup>	-	-	-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
3.	Chilled/Frozen Cephalopods	5	2	1x10 <sup>5</sup>	1x10 <sup>6</sup>	-	-	-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
4.	Live Bivalve Molluscs*	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5.	Chilled/Frozen Bivalves	5	2	1x10 <sup>5</sup>	1x10 <sup>6</sup>	-	-	-	-	-	-	-	-	After Chilling/Freezing	Improvement in hygiene; Time-Temperature Control along value chain
6.	Frozen Cooked Crustaceans/Frozen Heat Shucked Mollusc	5	2	1x10 <sup>5</sup>	1x10 <sup>6</sup>	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	-	-	-	-	End of Manufacturing process	Improvement in hygiene; Selection of raw material; Time-Temperature Control along value chain; process control
7.	Dried/Salted and Dried Fishery Products	5	0	1x10 <sup>5</sup>		-	-	-	-	5	2	100	500	End of Manufacturing process	Improvement in hygiene; Selection of raw material; Adequate drying (water activity ≤ 0.78)
8.	Thermally Processed Fishery Products	Commercially Sterile**				-	-	-	-	-	-	-	-	End of Manufacturing process	Revalidation of thermal process

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Sl. No.	Product Category*	Aerobic Plate Count				Coagulase positive Staphylococci				Yeast &mold count				Stage where criterion applies	Action in case of unsatisfactory results
		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)		Sampling Plan		Limits (cfu/g)			
		n	c	m	M	n	c	m	M	n	c	m	M		
9.	Fermented Fishery Products	-	-	-	-	5	1	1x10 <sup>2</sup>	1x10 <sup>3</sup>	5	0	100		End of Manufacturing process	Improvement in hygiene; Selection of raw material
10.	Smoked Fishery Products	5	0	1x10 <sup>5</sup>		5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	-	-	-	-	End of Manufacturing process	Improvement in hygiene; Time-Temperature Control along value chain
11.	Accelerated Freeze Dried Fishery Products	5	0	1x10 <sup>4</sup>		5	0	100		-	-	-	-	End of Manufacturing process	Selection of raw material; Improvement in hygiene; along value chain
12.	Fish Mince/Surimi and Analogues	5	2	1x10 <sup>5</sup>	1x10 <sup>6</sup>	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	-	-	-	-	End of Manufacturing process	Selection of raw material; Improvement in hygiene
13.	Fish Pickle	5	0	1x10 <sup>3</sup>		5	1	1x10 <sup>2</sup>	1x10 <sup>3</sup>	5	0	100		End of manufacturing process (before packing)	Improvement in hygiene; Control of pH/acidity, selection of ingredients
14.	Battered and Breaded Fishery Products	5	2	1x10 <sup>5</sup>	1x10 <sup>7</sup>	5	1	1x10 <sup>2</sup>	1x10 <sup>3</sup>	5	0	100		End of Manufacturing process	Improvement in hygiene; Time-Temperature Control
15.	Convenience Fishery Products	5	2	1x10 <sup>3</sup>	1x10 <sup>4</sup>	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	-	-	-		End of Manufacturing process	Improvement in hygiene; Time-Temperature control of batter mix
16.	Powdered Fish Based Products	5	2	1x10 <sup>4</sup>	1x10 <sup>5</sup>	5	2	1x10	1x10 <sup>2</sup>	5	0	100		End of Manufacturing process	Improvement in hygiene; Selection of raw material
	Test method	IS: 5402/ISO 4833				IS 5887 : Part 2 or IS 5887 Part 8 (Sec 1)/ ISO : 6888-1 or IS 5887 Part 8 (Sec 2)/ISO 6888-2				IS:5403/ISO 21527					

\*\* Commercial sterility should be established as per APHA (2015). Canned Foods—Tests for Commercial Sterility. Compendium of Methods for the Microbiological Examination of Food.

# No hygienic indicators are currently prescribed for the Live Bivalve Molluscs

**Table 1B**  
**Microbiological Requirements for Fish and Fishery Products—Safety Indicator Organisms**

Sl. No.	Product Category*	<i>Escherichia coli</i>				<i>Salmonella</i>				<i>Vibrio cholerae</i> (O1 and O139)				<i>Listeria monocytogenes</i>				<i>Clostridium botulinum</i>			
		Sampling Plan		Limits (MPN/g)		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits		Sampling Plan		Limits (MPN/g)	
		n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M	n	c	m	M
1.	Chilled/Frozen Finfish	5	3	11	500	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
2.	Chilled/Frozen Crustaceans	5	3	11	500	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
3.	Chilled/frozen Cephalopods	5	0		20	5	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
4.	Live Bivalve Molluscs	5	1	230/100g	700/100g	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5.	Chilled/Frozen Bivalves	5	0		46	10	0	Absent/25g		5	0	Absent/25g		-	-	-	-	-	-	-	-
6.	Frozen cooked crustaceans/Frozen heat shocked mollusca	5	2	1	10	5	0	Absent/25g		5	0	Absent/25g		5	0	Absent/25g		-	-	-	-
7.	Dried/ Salted and dried fishery products	5	0		20	5	0	Absent/25g		-	-	-	-	-	-	-	-	-	-	-	-
8.	Thermally processed fishery products	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of <i>Clostridium botulinum</i> and absence of botulinum toxin.			
9.	Fermented fishery products	5	2	4	40	10	0	Absent/25g		-	-	-	-	-	-	-	-	Absence of viable spores or vegetative cells of <i>Clostridium botulinum</i> and absence of botulinum toxin.			

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10.	Smoked fishery products	5	3	11	500	5	0	Absent/25g	5	0	Absent/25g	5	0	Absent/25g	-	-	-	-		
11.	Accelerated Freeze Dried Fishery Products	5	0		20	5	0	Absent/25g	5	0	Absent/25g	5	0	Absent/25g	-	-	-	-		
12.	Fish Mince/Surimi and analogues	5	0		20	5	0	Absent/25g	5	0	Absent/25g	5	0	Absent/25g	-	-	-	-		
13.	Fish Pickle	5	0		20	5	0	Absent/25g	-	-	-	-	-	-	-	-	-	—		
14.	Battered and Breaded fishery products	5	2	11	500	5	0	Absent/25g	5	0	Absent/25g	5	5	Absent/25g	-	-	-	-		
15.	Convenience fishery products	5	2	1	10	5	0	Absent/25g	5	0	Absent/25g	5	0	Absent/25g	-	-	-	-		
16.	Powered Fish based products	-	-	-	-	5	0	Absent/25g	-	-	-	-	-	-	-	-	-	—		
	Test Methods	IS: 5887 Part1 or ISO 16649-2				IS: 5887 Part 3/ ISO 6579			Vibrio, Bacteriological Analytical Manual, Chapter 9. USFDA BAM Online, May 2004				IS: 14988, Part 1&2/ISO 11290-1 & 2				IS:5887, Part 4 or ISO 17919			

#### Sampling Plan:

The terms n, c, m and M used in this standard have the following meaning:

n = Number of units comprising a sample.

c = Maximum allowable number of units having microbiological counts above m.

m = Microbiological limit that may be exceeded number of units c.

M = Microbiological limit that no sample unit may exceed.

#### Product Definitions:

- Chilled/Frozen Finfish includes clean and wholesome finfish, which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices. Chilling is the process of cooling fish or fish products to a temperature approaching that of melting ice. Chilling can be achieved either by using ice, chilled water, ice slurries of both seawater and freshwater or refrigerated seawater. Similarly, freezing is the process which is sufficient enough to reduce the temperature of the whole product to a level low enough to preserve the inherent quality of the fish and that have been maintained at this low temperature during transportation, storage and distribution up to and including the time of final sale. Freezing process that is carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The quick freezing process shall not be regarded as complete unless and until the product temperature reached  $-18^{\circ}\text{C}$  ( $0^{\circ}\text{F}$ ) or lower at the thermal centre after thermal stabilization.

- (2) Chilled/Frozen Crustaceans includes clean, whole or peeled crustaceans (shrimp/prawn, crabs and lobster) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (3) Chilled/Frozen Cephalopods includes cleaned, whole or de-skinned cephalopods (squid, cuttlefish and octopus) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (4) Live Bivalve Molluscs includes Oyster, Clam, Mussel, Scallop, Abalone which are alive immediately prior to consumption. Presentation includes the shell. Live bivalve molluscs are harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification, like relaying or depuration, prior to human consumption. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction.
- (5) Chilled/Frozen Bivalves includes clean, whole or shucked bivalves, which are live either in chilled or frozen condition and handled in accordance with good manufacturing practices. This product category includes filter feeding aquatic animals such as oysters, mussels, clams, cockles and scallops.
- (6) Frozen cooked Crustaceans or Frozen heat shucked Mollusca means clean, whole or peeled crustaceans, which are cooked at a defined temperature and time and subsequently frozen. Cooking of crustaceans must be designed to eliminate six log reduction of most heat resistant vegetative bacteria i.e. *Listeria monocytogenes*. Frozen heat shucked mollusca includes bivalves where meat is removed from the shell by subjecting the animals to mild heat before shucking to relax the adductor muscle and subsequently frozen.
- (7) Dried or Salted and Dried fishery Products means the product prepared from fresh or wholesome finfish or shellfish after drying with or without addition of salt. The fish shall be bled, gutted, beheaded, split or filleted and washed prior to salting and drying. Salt used to produce salted fish shall be clean, free from foreign matter, and has no visible signs of contamination with dirt, oil, bilge or other extraneous materials.
- (8) Thermally Processed Fishery Products means the product obtained by application of heat or temperature for sufficient time to achieve commercial sterility in hermetically sealed containers.
- (9) Fermented Fishery Products includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Non-traditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.
- (10) Smoked Fishery Products means fish or fishery product subjected to a process of treatment with smoke generated from smouldering wood or plant materials. Here the product category refers to hot smoked fish where fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete coagulation of the proteins in the fish flesh.
- (11) Accelerated Freeze dried Fishery Products means fish, shrimp or any fishery product subjected to rapid freezing, followed by drying under high vacuum so as to remove the water by sublimation to a final moisture content of less than two percent.
- (12) Fish Mince/Surimi and analogues means comminuted, mechanically removed meat which have been separated from and are essentially free from bones, viscera and skin. Surimi is the stabilized myofibrillar proteins obtained from mechanically deboned fish flesh that is washed with water and blended with cryoprotectants. Surimi analogues are variety of imitation products produced from surimi with addition of ingredients and flavor.
- (13) Fish Pickle means an oily, semi-solid product with spices and acidic taste obtained from maturation of partially fried fish with vinegar. It is produced by frying edible portions of fish, shrimp or mollusc, followed by partial cooking with spices, salt and oil and maturing for 1-3 days with added organic acids. The product is intended for direct human consumption as a seasoning, or condiment for food.

- (14) Battered and Breaded Fishery Products include fish portions, fillets or mince coated with batter and/or breading. Batter means liquid preparation from ground cereals, spices, salt, sugar and other ingredients and/or additives for coating. Typical batter types are non-leavened batter and leavened batter. Breading means dry breadcrumbs or other dry preparations mainly from cereals with colourants and other ingredients used for the final coating of fishery products.
- (15) Convenience Fishery Products are tertiary food products made of fish, which are in ready to eat form and also includes snack based items prepared from fish and fishery products meant for direct human consumption such as extruded fishery products, fried items namely fish wafers, crackers, fish cutlets, fish burgers and other such products. These products can be consumed directly after minimal handling and processing. This category includes Sous-vide cooked products, surimi-based products cooked (in-pack), pasteurized crab meat, pasteurized molluscs which are distributed as refrigerated, but meant for direct human consumption with minimal or no cooking.
- (16) Powdered Fish based Products include the products which are prepared from finfish/shellfish or parts thereof, with or without other edible ingredients in powdered form, suitable for human consumption. These may be consumed directly or as supplements and also after hydration and this category includes powdered and dried fish products generally used as ingredients in food preparations such as fish soup powder, fish chutney powder, ready to use fish-mix, and such other food. "

PAWAN KUMAR AGARWAL, Chief Executive Officer

[ADVT.-III/4/Extry/411/16]

Note. - The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number F. No. 2-15015/30/2010, dated the 1st August, 2011 and subsequently amended vide notification numbers:-

- (i) F.No.4/15015/30/2011, dated the 7th June, 2013;
- (ii) F.No.P.15014/1/2011-PFA, dated the 27th June, 2013;
- (iii) F.No.5/15015/30/2012, dated the 12th July, 2013;
- (iv) F.No.P.15025/262/13-PA/FSSAI, dated the 5th December, 2014;
- (v) F.No.1-83F/Sci.Pan-Noti/FSSAI-2012, dated the 17th February, 2015;
- (vi) F.No.4/15015/30/2011, dated the 4th August, 2015;
- (vii) F.No.P.15025/263/13-PA/FSSAI, dated the 4th November, 2015;
- (viii) F.No.P.15025/264/13-PA/FSSAI, dated the 4th November, 2015;
- (ix) F.No.7/15015/30/2012, dated the 13th November, 2015;
- (x) F.No.P.15025/208/2013-PA/FSSAI, dated the 13th November, 2015;
- (xi) F.No.P.15025/261/2013-PA/FSSAI, dated the 13th November, 2015;
- (xii) F.No.1-10(1)/Standards/SP (Fish and Fisheries Products)/FSSAI-2013, dated the 11th January, 2016;
- (xiii) No. 3-16/ Specified Foods/Notification(Food Additive)/FSSAI-2014, dated the 3rd May, 2016;



- (xiv) F.No. 15-03/Enf/FSSAI/2014, dated the 14th June, 2016;
- (xv) No. 3-14F/Notification(Nutraceuticals)/FSSAI-2013, dated the 13th July 2016;
- (xvi) F.No. 1-12/Standards/SP (Sweets, Confectionery)/ FSSAI-2015, dated the 15th July 2016;
- (xvii) F.No. 11/09/Reg/Harmoniztn/2014, dated the 5th September 2016;
- (xviii) Stds/CPLQ CP/EM/FSSAI-2015, dated the 14th September 2016;
- (xix) F. No.1-110(2)/SP (Biological Hazards)/FSSAI/2010, dated the 10th October 2016;
- (xx) F.No.11/12/Reg/Prop/FSSAI-2016, dated the 10th October 2016;
- (xxi) F. No.1-110(2)/SP (Biological Hazards)/FSSAI/2010, dated the 10th October, 2016;
- (xxii) F.No. Stds/ SP (Water & Beverages) Notif(2)/FSSAI-2016, dated the 25th October, 2016;
- (xxiii) F. No. P.15025/93/2011-PFA/FSSAI, dated the 2nd December, 2016;
- (xxiv) F. No. P.15025/6/2004-PFS/FSSAI, dated the 29th December, 2016;
- (xxv) F.No.Stds/O&F/Notification(1)/FSSAI-2016, dated the 31st January, 2017; and
- (xxvi) F.No. 1-12/Standards/2012-FSSAI, dated the 10th February, 2017.